

LAW OFFICES
CAREY, SCOTT, DOUGLAS & KESSLER, PLLC
901CHASE TOWER
707 VIRGINIA STREET, EAST
P. O. BOX 913
CHARLESTON, WV 25323

MICHAEL W. CAREY
ROBERT E. DOUGLAS
JOHN A. KESSLER
S. BENJAMIN BRYANT
DAVID R. POGUE

TELEPHONE (304) 345-1234
TELEPHONE (304) 342-1111
FACSIMILE (304) 342-1105

April 17, 2020

VIA EMAIL ONLY
April.L.Robertson@wv.gov

April L. Robertson, General Counsel
Office of Cabinet Secretary Bill J. Crouch
WV Department of Health & Human Resources
One Davis Square, Suite 100
Charleston, WV 25301

Re: The City of Huntington, et al. v. AmerisourceBergen Drug Corporation, et al.
Civil Action No(s). 3:17-01362 and 3:17-01665

Dear Ms. Robertson,

Thank you for accepting service of the enclosed subpoena directed to Bill J. Crouch. We look forward to working cooperatively on this matter. We are aware of the difficulties posed by the current COVID-19 pandemic, and recognize it may impact subpoena compliance and scheduling, but cannot defer serving this subpoena due to upcoming Court-imposed deadlines. We will do our best to accommodate reasonable requests, mindful of our obligations under the existing case schedule.

In this regard, please note that while the enclosed subpoena requires both the production of documents and attendance at a deposition, the deposition date in the subpoena is a suggested date. We are willing to reschedule the deposition for a mutually acceptable alternative date that is earlier or later, subject to two limiting factors: (1) we cannot take the deposition until after the requested documents have been produced (which we understand may be delayed by the COVID-19 pandemic); and (2) due to the Court-imposed June 15, 2020 deadline for completing all fact discovery, the deposition must be scheduled to take place no later than June 15.

Thank you for your attention to this matter during this difficult time.

Sincerely,



David R. Pogue

DRP/nes

UNITED STATES DISTRICT COURT
for the
Southern District of West Virginia

| | | |
|--|---|---|
| City of Huntington; Cabell County Commission |) | |
| <i>Plaintiff</i> |) | |
| v. |) | Civil Action No. 3:17-01362; 3:17-01665 |
| AmerisourceBergen Drug Corporation, et al. |) | |
| <i>Defendant</i> |) | |

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: BILL J. CROUCH
c/o April L. Robertson, General Counsel, Office of Cabinet Secretary Bill J. Crouch

(Name of person to whom this subpoena is directed)

Testimony: YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

| | | |
|--|----------------|---------------------|
| Place: Carey, Scott, Douglas & Kessler, PLLC 707 Virginia St. East, Suite 901, Charleston, WV 25301 Or another mutually convenient location | Date and Time: | 06/08/2020 10:00 am |
|--|----------------|---------------------|

The deposition will be recorded by this method: **Stenography and Video**

Production: You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

SEE SCHEDULE A

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 04/17/2020

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (*name of party*) Cardinal Health, Inc
David R. Pogue, Carey, Scott, Douglas & Kessler, PLLC, who issues or requests this subpoena, are:
707 Virginia Street, East, Charleston, WV 25301; drpogue@csdlawfirm.com; 304-345-1234

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)**(c) Place of Compliance.**

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

Pursuant to Rule 45 of the Federal Rules of Civil Procedure, Cardinal Health, Inc. hereby serves the following Requests for Production of Documents on **Bill Crouch**.

DEFINITIONS

The following terms shall have the meanings set forth below. Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Rules of Procedure for the Southern District of West Virginia.

1. “You” and “Your” shall mean the person to whom this subpoena duces tecum is addressed, including all agents, employees, and other persons acting or authorized to act on his or her behalf.
2. “Communication” has the full meaning ascribed to it by Local Rule of Civil Procedure 26.2(c)(1), and means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Document” has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a) and Local Rule of Civil Procedure 26.2(c)(2), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any

form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in the possession, custody, or control of the person to whom this subpoena duces tecum is addressed. “Documents” include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.

4. “Person” has the full meaning ascribed to it by Local Rule of Civil Procedure 26.2(c)(6), and means any natural person or any business, legal or governmental entity or association.
5. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients only through prescriptions written by duly licensed and DEA registered prescribers.
6. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not approved by FDA, including but not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, and counterfeit opioid medications.

7. “Relating to,” “Referring to,” or “Concerning,” when referring to any given subject matter, means any Document that constitutes, comprises, involves, contains, embodies, reflects, identifies, states, mentions, alludes to, refers directly or indirectly to the particular subject matter identified.
8. “Agency” means any office, division, department, board, commission, task force, committee, working group, council, bureau, unit, branch, organization, and/or association, formal or informal, whether a component of a larger entity or a stand-alone entity.
9. “Plaintiffs” means the plaintiffs named in this action, the City of Huntington and Cabell County, including but not limited to, its executive and legislative branches, agencies, offices, departments, divisions, commissions, committees, subcommittees, boards, directors, administrators, employees, officers, directors, shareholders, agents, contractors, vendors, instrumentalities, representatives, counsel, and all Persons and entities acting or purporting to act under their control or on their behalf.
10. “Defendants” means all defendants named in *City of Huntington v. AmerisourceBergen Drug Corp., et al.*, Civil Action No. 3:17-01362, and *Cabell County Commission v. AmerisourceBergen Drug Corp., et al.*, Civil Action No. 3:17-01665, as of the date of this notice, and their present or former officers, directors, shareholders, employees, agents, representatives, counsel and all persons and entities acting or purporting to act under their control or on their behalf.

INSTRUCTIONS

1. Unless otherwise agreed in writing, all Documents are to be produced to the attention of David R. Pogue, Carey, Scott, Douglas & Kessler, PLLC, 707 Virginia Street, East, Suite 901, Charleston, WV 25301.
2. Unless otherwise indicated, these Requests cover the entire timeframe for which any of the requested documents have actually been maintained regardless of any applicable records retention policy.
3. Documents that are in paper form or that constitute other physical objects from which recorded information may be visually read, as well as audio or video tapes or text messages and similar recordings, should be produced in their original form or in copies that are exact duplicates of the originals. Computer files and similar electronic records should be produced in a readable form.
4. Should You consider any of the documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, please designate those documents as such under the operative Protective Order in this case (copy attached).
5. Should You determine that any of the documents requested contain personal health information that may not be disclosed pursuant to HIPAA or analogous state law, please redact that information and assign in its place a unique identifier.
6. Except as otherwise specified, the timeframe for these requests is January 1, 1996 through the present.

DOCUMENTS TO BE PRODUCED

1. All Documents and Communications discussing, referring, or relating to the standard of care for prescribing and dispensing Prescription Opioids.
2. All Documents and Communications discussing, referring, or relating to any guidance, continuing education, training, presentations, policies, procedures, programming, or resources that You received from any Person or that You provided to any Person regarding Prescription Opioids.
3. All Documents and Communications relating to the legitimate need for or use of Prescription Opioids—meaning any need for and/or use of Prescription Opioids that You do not contend would be unlawful or harmful—and the responsibilities and obligations of physicians to treat pain patients.
4. All Documents and Communications concerning any efforts You have made to encourage the prescribing and use of Prescription Opioids.
5. All Documents and Communications concerning any efforts You have made to discourage the prescribing, abuse, or diversion of Prescription Opioids.
6. All Documents and Communications You prepared, received, or considered concerning the dangers, side effects, and addiction risks of Prescription Opioids, and/or ways to combat the problem of abuse and diversion of Prescription Opioids.
7. All Documents and Communications You prepared, received, or considered concerning the benefits, efficacy, and legitimate uses of Prescription Opioids in the treatment of pain.
8. All Documents and Communications discussing, referring, or relating to Your knowledge of unlawful prescribing, dispensing, use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, theft, and trafficking of Prescription Opioids or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County, or the State of West Virginia.
9. All Documents and Communications that state, discuss, reflect, or suggest recommendations for actions to be taken by You or any federal, state, or local Agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, or the State of West Virginia, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription Opioids or Illicit Opioids.
10. All Documents and Communications discussing, referring, or relating to Your understanding of the “opioid epidemic” in the City of Huntington, Cabell County, or any town, village, or city within Cabell County, or the State of West Virginia, the point in time in which You identified the “opioid epidemic,” any investigation by You of the cause of the “opioid epidemic,” and any response, training, guidance, laws, regulations,

continuing education, or efforts to abate You have developed or undertaken in response to the “opioid epidemic.”

11. All documents produced by You in any litigation related to the manufacturing, marketing, or distribution of Prescription Opioids, including but not limited to *In National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP (N.D. Ohio) and *State of Oklahoma ex rel. Hunter v. Purdue Pharma LP et al.*, Case No. CJ-2017-816 (Okla. Dist. Ct.—Cleveland Cty.).
12. All Documents and Communications concerning any studies, reports, investigations, or analyses regarding actual or suspected misuse, abuse, or diversion of Prescription Opioids about which You had knowledge, including but not limited to those that You prepared, received, or participated in. This includes, but is not limited to, all Documents concerning Your participation in the preparation, planning, drafting and publication of: (a) “Opioid Response Plan for the State of West Virginia,” and the initiatives contained therein, as found here, <https://dhhr.wv.gov/bph/Documents/ODCP%20Response%20Plan%20Recs/Opioid%20Response%20Plan%20for%20the%20State%20of%20West%20Virginia%20January%202018.pdf>; (b) “2016 West Virginia Overdose Fatality Analysis: Healthcare Systems Utilization, Risk Factors, and Opportunities for Intervention,” and the data and analyses contained therein, as reflected in part here, https://dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf; and (c) “West Virginia 2020-2022 Substance Use Response Plan, and the initiatives contained there, as found here, [https://dhhr.wv.gov/office-of-drug-control-policy/news/Documents/FINAL%20-%20West%20Virginia%202020_2022%20Council%20Substance%20Use%20Plan_January%202020.%202020%20\(as%20filed\).pdf](https://dhhr.wv.gov/office-of-drug-control-policy/news/Documents/FINAL%20-%20West%20Virginia%202020_2022%20Council%20Substance%20Use%20Plan_January%202020.%202020%20(as%20filed).pdf).
13. All Documents and Communications reflecting or concerning Your involvement in drafting, amending, assessing, introducing, lobbying for or against, implementing, administering, enforcing, and/or monitoring or analyzing compliance with or the effect of legislation, statutes, rules, regulations, or guidelines concerning Prescription Opioids and Illicit Opioids, including but not limited to the Intractable Pain Act (West Virginia Code § 30-3A-1 et seq.), Senate Bill 437 (2012) (amending several articles of West Virginia Code related to the Controlled Substance Monitoring Program database), Senate Bill 339 (2017) (West Virginia Code § 16-52-1 et seq.) (creating the Coalition for Responsible Chronic Pain Management), U.S. Center for Disease Control Guideline for Prescribing Opioids for Chronic Pain, United States, 2016, the West Virginia Drug Control Policy Act (West Virginia Code § 15-5T-2), and the Opioid Reduction Act (West Virginia Code § 16-54-1 et seq.).
14. All Documents and Communications discussing, referring, or relating to the West Virginia Department of Health and Human Resources’ responses, actions, investigations, guidance, rules, and/or regulations concerning Prescription Opioids or Illicit Opioids, or funding thereof, including but not limited to the Opioid Response Plan and the Office of Drug Control Policy.

15. All Documents reflecting or concerning Your involvement in the Governor's Advisory Council on Substance Abuse, which was created by Governor Earl Ray Tomblin by Executive Order 5-11 on September 6, 2011, reestablished by Governor Jim Justice as the Governor's Advisory Council on Substance Use Disorder Policy by Executive Order 10-17 on December 20, 2017, and further reestablished by Governor Jim Justice as the Governor's Council on Substance Abuse Prevention and Treatment by Executive Order 22-18 on December 3, 2018.
16. All Documents concerning any Communications or interactions You have had with industry trade groups and associations concerning Prescription Opioid use, misuse, abuse, and diversion, including but not limited to interactions with the (a) Healthcare Distribution Management Association, (b) Healthcare Distribution Alliance, (c) Pain Care Forum, (d) National Association of Chain Drug Stores, (e) Pharmaceutical Research and Manufacturers of America, (f) West Virginia Pharmacists Association, (g) American Society of Consultant Pharmacists, (h) American Pharmacists Association, (i) Federation of State Medical Boards, (j) American Academy of Pain Medicine, (k) Alliance for Patient Access, (l) U.S. Pain Foundation, (m) West Virginian Hospital Association, (n) West Virginia State Medical Association, (o) West Virginia Health Care Association, and/or (p) American Geriatrics Society.
17. All Documents concerning any Communications or interactions You have had with Plaintiffs concerning the prescribing, dispensing, use, misuse, abuse, sale, diversion, production, distribution, purchase, or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County, or the State of West Virginia.
18. All Documents concerning any Communications or interactions You have had concerning the prescribing, dispensing, use, misuse, abuse, sale, diversion, production, distribution, purchase, or trafficking of Prescription Opioids, with entities including but not limited to, interactions with (a) pharmacies or pharmacists, including, but not limited to, individuals associated with a school of pharmacology, (b) the West Virginia Board of Pharmacy, (c) the West Virginia Board of Medicine, (d) the West Virginia Board of Osteopathic Medicine, (e) the West Virginia State Board of Examiners for Licensed Practical Nurses, (f) the West Virginia State Board of Examiners for Registered Professional Nurses, (g) the West Virginia Board of Dentistry, (h) doctors, hospitals, treatment centers, and other healthcare providers, including, but not limited to, individuals associated with a school of medicine, dentistry, or nursing, (i) patients and beneficiaries, (j) pharmacy benefit managers, (k) drug manufacturers, (l) drug wholesalers and distributors, including Defendants, (m) federal government agencies and law enforcement, (n) state and local agencies and law enforcement, including, but not limited to, agencies related to child and family services and public health, (o) the West Virginia Controlled Substances Monitoring Program, and/or (p) policymakers and government officials within legislative or administrative bodies.

19. All Documents and Communications discussing, referring to, or relating to improper or wrongful conduct by Defendants or any other distributors, prescribers, pharmacies, or other healthcare providers related to Prescription Opioids.
20. All Documents and Communications discussing, referring to, or relating to Your provision of healthcare management and consulting services to hospitals, long-term care facilities, ambulatory care clinics, and physicians concerning Prescription Opioids.
21. All Documents and Communications discussing, referring to, or relating to Your partnership in a long-term care company that owns and manages nursing facilities and assisted living communities in West Virginia and use, misuse, abuse, and diversion of Prescription Opioids.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 1 of 38. PageID #: 5799

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

Case No.: 1:17-md-2804-DAP

This document relates to:

Honorable Dan Aaron Polster

All Cases

CASE MANAGEMENT ORDER NO. 2: PROTECTIVE ORDER

I. Scope of Order

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there ("the Litigation"). All materials produced or adduced in the course of

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 2 of 38. PageID #: 5800

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Definitions

7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 3 of 38. PageID #: 5801

Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 4 of 38. PageID #: 5802

except as provided in Paragraphs 33 or 34.

10. Confidential Information. "Confidential Information" is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. Highly Confidential Information. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 5 of 38. PageID #: 5803

Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

12. **Manufacturer Defendant:** Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. **Distributor Defendant:** Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.

14. **Retail Defendant:** Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. **Receiving Party.** "Receiving Party" means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. **Producing Party.** "Producing Party" means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. **Protected Material.** "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" or "Highly Confidential" in accordance with this Protective Order.

18. **Outside Counsel.** "Outside Counsel" means any law firm or attorney who

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 6 of 38. PageID #: 5804

represents any Party for purposes of this litigation.

19. In-House Counsel. "In-House Counsel" means attorney employees of any Party.

20. Counsel. "Counsel," without another qualifier, means Outside Counsel and In-House Counsel.

21. Independent Expert. "Independent Expert" means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. "This Litigation" means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

III. Designation and Redaction of Confidential Information

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 7 of 38. PageID #: 5805

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 8 of 38. PageID #: 5806

qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 9 of 38. PageID #: 5807

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 10 of 38. PageID #: 5808

Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

IV. Access to Confidential and Highly Confidential Information

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.I) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 11 of 38. PageID #: 5809

that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 12 of 38. PageID #: 5810

- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 13 of 38. PageID #: 5811

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 14 of 38. PageID #: 5812

that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 15 of 38. PageID #: 5813

- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 16 of 38. PageID #: 5814

agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 17 of 38. PageID #: 5815

36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

V. Confidentiality Acknowledgment

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 18 of 38. PageID #: 5816

VI. Litigation Experts and Consultants.

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 19 of 38. PageID #: 5817

consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

VII. Protection and Use of Confidential and Highly Confidential Information

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 20 of 38. PageID #: 5818

Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 21 of 38. PageID #: 5819

shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 22 of 38. PageID #: 5820

48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;¹ or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

¹ The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 23 of 38. PageID #: 5821

VIII. Changes in Designation of Information

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 24 of 38. PageID #: 5822

Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 25 of 38. PageID #: 5823

images, and associated production information as provided above.

IX. Inadvertent Production of Documents

53. **Non-Waiver of Privilege.** The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. **Notice of Production of Privileged Information.** If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 26 of 38. PageID #: 5824

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;
- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database, where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 27 of 38. PageID #: 5825

described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 28 of 38. PageID #: 5826

and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

X. Filing and Use at Trial of Protected Material

62. Only Confidential or Highly Confidential portions of relevant documents

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 29 of 38. PageID #: 5827

are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 30 of 38. PageID #: 5828

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

XI. Information or Highly Confidential Information Requested by Third Party; Procedure Following Request.

66. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 31 of 38. PageID #: 5829

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 32 of 38. PageID #: 5830

XII.HIPAA-Protected Information

70. General. Discovery in this Litigation may involve production of "Protected Health Information" as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. "Protected Health Information" shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 ("Covered Entities") or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 ("Business Associate") in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material "Confidential Protected Health Information" in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as "Confidential Protected Health Information" shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Protected Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as "Confidential Protected Health

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 33 of 38. PageID #: 5831

Information" shall be made in the following manner: (a) or documents, by placing the notation "Confidential Protected Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Protected Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Protected Health Information" both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being "Confidential Protected Health Information" at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 34 of 38. PageID #: 5832

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 35 of 38. PageID #: 5833

production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

XIV. Miscellaneous Provisions

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or used in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 36 of 38. PageID #: 5834

Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

IT IS SO ORDERED.

Dated: 5/15/18

/s/Dan Aaron Polster
Honorable Dan Aaron Polster
United States District Judge

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 37 of 38. PageID #: 5835

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

Case No.: 1:17-md-2804-DAP

This document relates to:

Honorable Dan Aaron Polster

All Cases

EXHIBIT A TO CASE MANAGEMENT ORDER NO. _____

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No.) that was issued by the United States District Court for the Northern District of Ohio on , 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Case: 1:17-md-02804-DAP Doc #: 441 Filed: 05/15/18 38 of 38. PageID #: 5836

Date: _____

City and State where sworn and signed: _____

Printed Name: _____

Signature: _____

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 1 of 9. PageID #: 418591

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

| | | |
|------------------------------------|----------|--------------------------------|
| IN RE NATIONAL PRESCRIPTION |) | CASE NO. 17-MD-2804 |
| OPIATE LITIGATION |) | SPECIAL MASTER COHEN |
| This document relates to: |) | |
| All Cases |) | |
| |) | AMENDMENTS TO CMO NO. 2 |
| |) | RE: CONFIDENTIALITY AND |
| |) | <u>PROTECTIVE ORDER</u> |

The parties have agreed to make certain amendments to various paragraphs contained in the Court's Case Management Order No. 2 (docket no. 441) which address confidentiality and Protective Order issues. The parties submitted other proposed amendments upon which they could not agree. The Special Master now adopts the parties' agreed-upon revisions and also resolves the parties' disagreements, and amends CMO-2 accordingly, as set out in the attached document.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: September 29, 2019

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 2 of 9. PageID #: 418592

**AMENDMENTS TO CONFIDENTIALITY & PROTECTIVE ORDER PROVISIONS
OF CMO NO. 2 (docket no. 441)**

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential. Parties shall not be overly broad in designating materials as Confidential or Highly Confidential under this Protective Order. If a Party is repetitively, overly broad in designating materials as Confidential or Highly Confidential, that Party risks having large categories of such designations denied protection. The Court expects and will assume that the attorney submitting the designation has reviewed it and does so subject to Rule 11.

10. **Confidential Information.** "Confidential Information" is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute, or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Information, protected law enforcement materials (including investigative files, overdoes records, Narcan records, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. **Highly Confidential Information.** "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 3 of 9. PageID #: 418593

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed. Any Confidential or Highly Confidential designations of deposition testimony by a party shall occur only if an attorney for that party has, in good faith, determined that the material is entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and the rulings of the Special Master and the Court. The Designating Party shall make page and line designations of deposition testimony; global designation of deposition testimony as Confidential or Highly Confidential is not permitted.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34 below, along with the witness and the witness's counsel, may be present if any questions regarding Confidential Information or Highly Confidential Information are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "Confidential" or "Highly Confidential" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. Any such designation may only be made after an attorney for the Designating Party has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 4 of 9. PageID #: 418594

information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same duties and rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production any document, or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document, that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Confidential Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the document and/or in the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact or de-identify:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information), (b) individuals in clinical studies or adverse event reports whose identity is protected by law, (c) undercover law enforcement personnel and confidential informants, and (d) patient identified information that is protected by 42 CFR 2.12 and associated regulations consistent with the Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases [Dkt. 1421].

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work-product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce documents in litigation.

Plaintiffs may withhold or redact the following specific protected information: (a) records of ongoing criminal investigations, and (b) records or information provided to the party by DEA, FBI, or other state or federal law enforcement agency that such agency designates is of a sensitive nature. The fact of redacting or withholding does not create a presumption that the redaction or withholding is valid, and Receiving Parties can challenge redactions freely after providing

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 5 of 9. PageID #: 418595

appropriate notice to the Producing Party and (if applicable) the agency asserting the privilege or confidentiality redaction.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.L) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;
- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 6 of 9. PageID #: 418596

Designating Party may request a meet and confer and may seek a protective order from the Court.

- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or
- m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to In-House Counsel of another Defendant, provided that the In-House Counsel (i) has regular involvement in the Litigation (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 7 of 9. PageID #: 418597

- A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential Information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
 - c. Individual Parties that have produced the designated information;
 - d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
 - e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
 - f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
 - g. Any individual(s) who authored, prepared, or previously reviewed or received the information;
 - h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
 - i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
 - j. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 8 of 9. PageID #: 418598

and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party. To the extent that a Producing Party's Confidential or Highly Confidential Information becomes part of the public record in this proceeding, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public through the Court record, the specific testimony, document excerpts, or other evidence will become and remain public. However, a Receiving Party shall not unnecessarily attempt to insert materials designated as Confidential or Highly Confidential into the Court record solely for purposes of making them public. Once information is made public, it is not confidential even if continued to be marked as such by the Producing Party, and the Receiving Party may freely use such information. A Receiving Party does not need to challenge Confidential or Highly Confidential designations of specific testimony, documents, or other evidence excerpts that become part of the public record in this proceeding. A Receiving Party can also challenge a designation for other testimony or portions of the excerpted document or other evidence as set forth in paragraph 52 below.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document or deposition are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing, of its reasons why the confidentiality designation was not proper and must: (a) give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation, and (b) offer to provide the Producing Party with multiple alternatives (dates and times) to meet and confer during the seven (7) day period following the date of the

Case: 1:17-md-02804-DAP Doc #: 2688 Filed: 09/29/19 9 of 9. PageID #: 418599

Receiving Party's written challenge notification. Thereafter, if a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party, and the Receiving Party shall have seven (7) days from such notification to challenge the designation with the Court or Special Master. These time periods may be modified in emergent circumstances, as agreed to by the Challenging and Designating Parties, or as ordered by the Special Master or the Court. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the event that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media, images, and associated production information as provided above. The parties are hereby notified that Discovery Ruling No. 20 Regarding Confidentiality Designations (Doc. 1650), as well as the "ARCOS Ruling" by the Sixth Circuit Court of Appeals (docket no. 1710), provide relevant legal standards, principles, and examples which should be followed and/or used as guidance relative to disputes over materials designated as Confidential or Highly Confidential at the discovery stage of the litigation.

Case: 1:17-md-02804-DAP Doc #: 2687 Filed: 09/29/19 1 of 4. PageID #: 418587

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

| | | |
|------------------------------------|----------|--|
| IN RE NATIONAL PRESCRIPTION |) | CASE NO. 17-MD-2804 |
| OPIATE LITIGATION |) | SPECIAL MASTER COHEN |
| This document relates to: |) | |
| All Cases |) | AMENDMENT TO CMO NO. 2 |
| |) | <u>RE: INADVERTENT PRODUCTION</u> |

The parties have agreed to make certain amendments to "Section IX. Inadvertent Production of Documents," contained in the Court's Case Management Order No. 2 (docket no. 441). The Court approves these amendments, which are set out in the attached document.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: September 29, 2019

Case: 1:17-md-02804-DAP Doc #: 2687 Filed: 09/29/19 2 of 4. PageID #: 418588

REPLACING SECTION IX OF CMO NO. 2 (docket no. 441)

IX. Inadvertent Production of Documents

53. **Non-Waiver of Privilege.** The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and, pursuant to Federal Rule of Evidence 502(d), shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(b) and 502(d).

54. Notice of Production of Privileged Information.

a. **Notice by Designating Party.** If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, shall identify the type of privilege claimed, and may demand that the Receiving Party return or destroy the Privileged Information.

b. **Notice by Receiving Party.** In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. **Recall of Privileged Information.** If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;

Case: 1:17-md-02804-DAP Doc #: 2687 Filed: 09/29/19 3 of 4. PageID #: 418589

- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as described herein;
- vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and
- vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted (“Clawed-Back Information”), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information.

58. If, for any reason, the Designating Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Special Master pursuant to the procedures set forth in Case Management Order One and established by the Special Master. The Designating Party bears the burden of establishing the privileged or protected nature of any Privileged Information. For circumstances where the Parties are unable to reach an agreement, the procedure for submission to the Special Master is as follows:

- i. Receiving Party shall file its Motion to Compel and request for *in camera* submission to the Special Master with carbon copy to include only counsel for Receiving Party and Designating Party;

Case: 1:17-md-02804-DAP Doc #: 2687 Filed: 09/29/19 4 of 4. PageID #: 418590

- ii. Designating Party shall file its opposition on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to Receiving Party's counsel;
- iii. The Receiving Party shall file its reply (if any) on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to include only counsel for the Receiving Party and the Designating Party;
- iv. If necessary, a hearing shall be conducted just between the Designating Party, the Receiving Party, and the Special Master.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. [REMOVED BY AGREEMENT OF THE PARTIES]

61. Nothing in this Order overrides an attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the other Party that such materials have been produced.

Case: 1:17-md-02804-DAP Doc #: 2987 Filed: 12/13/19 1 of 5. PageID #: 431069

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION**

MDL No. 2804

This document relates to:

Case No. 17-md-2804

"Track Two Cases"

Special Master David Cohen

**PROTECTIVE ORDER REGARDING DISCLOSURE
BY PLAINTIFFS OF CONFIDENTIAL MEDICAL RECORDS**

WHEREAS, Distributor Defendants¹ served discovery upon the Track Two bellwether Plaintiffs which potentially requires the disclosure of protected health information governed by the Health Insurance Portability and Accountability Act of 1996 (hereinafter referred to as "HIPAA"); *R.K. v. St. Mary's Med. Ctr., Inc.*, 229 W. Va. 712, 735 S.E.2d 715 (2012); and

WHEREAS, this Court has addressed procedural safeguards to such disclosure throughout this litigation. See e.g., *Case Management Order No. 2: Protective Order* (Doc #: 441) (Doc #: 1357); *Track One Discovery Order Regarding Health-Related Information* (Doc #: 703); *Discovery Ruling No. 7* (Doc #: 1051); *November 21, 2018 Order* (Doc #: 1147); *Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases* (Doc #: 1421); *Order Governing Production of Non-Party OptumRx, Inc.'s Pharmacy Claims Data for Track One Cases* (Doc #: 1635); *Order Governing Production Of Non-Party Humana Health Plan of Ohio, Inc.'s Medical And Pharmacy Claims Data For Track One Cases* (Doc #: 1641); *Amendment to CMO*

¹ The Distributor Defendants are AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation.

Case: 1:17-md-02804-DAP Doc #: 2987 Filed: 12/13/19 2 of 5. PageID #: 431070

No. 2 Re. Confidentiality and Protective Order (Doc # 2688); Amendment to CMO No. 2 Re: Inadherent Production (Doc #: 2687); Agreed Order Governing Privilege (Doc #: 2882); and

WHEREAS, the bellwether Plaintiffs desire to efficiently advance this litigation while preserving the privacy rights of the general public; and

WHEREAS, federal law provides this Court with the authority to compel the disclosure of protected health information while providing adequate safeguards; and

WHEREAS, the Plaintiffs and Distributor Defendants agree to the provisions below; now therefore

IT IS HEREBY ORDERED that the following provisions shall govern the production of protected health information in the Track Two Cases:

1. **Findings.** The Court hereby makes the following findings with respect to the production of protected health information:

- a. Good cause exists for the entry of this Order.
- b. Alternative methods of obtaining this information are not available or would not be effective.
- c. The public interest and the need for disclosure of this information, subject to the restrictions set forth herein, outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.
- d. The bellwether Plaintiffs shall produce relevant protected health information not implicated by Title 42, Part 2 of the Code of Federal Regulations ("Part 2"), without redaction.

Case: 1:17-md-02804-DAP Doc #: 2987 Filed: 12/13/19 3 of 5. PageID #: 431071

e. Only those individuals who require the information for purposes of this litigation (as described below) may receive protected health information produced pursuant to this Order.

f. The procedures set forth herein are necessary to limit disclosure for the protection of the patient, the physician-patient relationship, and the treatment services.

3. **Designation.** Protected health information produced pursuant to this Order shall be produced with the following legend appearing in either the title of the electronic file or on the face of the document: "HIPAA PROTECTED HEALTH INFORMATION - ACCESS RESTRICTED TO ATTORNEYS AND EXPERTS."

4. **Restrictions on Disclosure.** All parties shall safeguard and maintain the confidentiality of this information pursuant to the terms of the HIPAA protective order (seedocket no. 441, CMO-2 at 32-34), and shall limit disclosure to attorneys and experts for the parties, unless otherwise ordered by the Court. Specifically, no person shall, without leave of Court, use any material produced pursuant to this Ruling in connection with any formal or informal third-party discovery of individuals or entities revealed, including but not limited to: (i) requests to or about individuals whose records are produced; and (ii) requests to health care providers or administrators concerning the treatment of individuals described therein. In sum, no person shall contact or attempt to contact any individual identified in the medical records, or their family members or medical providers or other related staff, for the purpose of obtaining additional information related to this case, without leave of Court. Nothing in this order shall prohibit a party from conducting otherwise-allowed discovery from or relating to a person as to whom HIPAA-protected data has

Case: 1:17-md-02804-DAP Doc #: 2987 Filed: 12/13/19 4 of 5. PageID #: 431072

been produced based on other information obtained, either in discovery or otherwise, concerning that person.

All protected health information produced pursuant to this Order shall be disclosed only to: (i) Outside Counsel for the parties in this action; (ii) in-house counsel for Defendants in this action with responsibility for overseeing this litigation; (iii) consulting and testifying experts retained specifically to provide services in this action; and (iv) court personnel and staff, including the Special Masters appointed in this action and their assistants. No other individuals shall be permitted to access protected health information, and all parties shall institute reasonable and appropriate steps to prevent against unauthorized disclosure.

5. Breach Notification. In the event that any Party learns of the unauthorized disclosure of protected health information subject to this Order, such Party shall provide prompt notification of the breach to counsel for each of the Track Two Plaintiffs, such notice to include: (1) the date of the breach; (2) the circumstances of the breach; (3) the identity or identities of the unauthorized recipients; and (4) all steps taken or planned to remedy the breach.

6. Limitations on Use. All protected health information produced pursuant to this Order has been produced solely for purposes of this litigation, and shall only be used for purposes of this litigation.

Case: 1:17-md-02804-DAP Doc #: 2987 Filed: 12/13/19 5 of 5. PageID #: 431073

7. Restrictions on Third-Party Discovery. All prior restrictions on the use of protected health information in connection with third party discovery remain in effect, including the limitations on third party discovery set forth in Discovery Ruling No. 7, as clarified by the Special Master.

Entered this the 13th day of December, 2019.

/s/**David R. Cohen**
Special Master